



OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION HEALTH EFFECTS DIVISION UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

APR 25 1997

MEMORANDUM

SUBJECT: Folpet. Storage Stability and Magnitude of the Residue in Melons, Onions,

Cranberries, Grapes, Lettuce, Tomatoes, Strawberries, Apples, and Cucumbers.

GDLN 860.1500

DP Barcodes: D234664, D234431, D234431, and D234355; CBRS Nos. D17890 and 17891; MRID Nos.: 442352-01, 442352-02, 442352-03, 442352-04, 442352-05, 442352-06, 442352-07, 442352-08, 442352-09, 442400-01, 442400-02, 442400-03, 442400-04, 442400-05, 442400-06, 442400-07, 442400-07, 442400-08, 442400-

08, and 442400-09. Case No. 0630.

FROM: David J. Miller, HSO, US Public Health Service

Chemistry Pilot Review Team

Chemistry Branch II--Reregistration Support

Health Effects Division (7509C)

THRU: R.B. Perfetti, Ph.D., Acting Branch Chief

Chemistry Branch II--Reregistration Support

Health Effects Division (7509C)

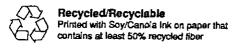
TO: Mary Clock, Chemical Review Manager

Reregistration Branch

Risk Characterization and Analysis Branch (7509C)

BACKGROUND

CBRS has been asked to review a series of magnitude of the residue study submissions on onions, cranberries, grapes, lettuce, tomatoes, strawberries, apples, melons, and cucumbers.



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The studies were submitted by Makhteshim-Agan as part of the requirements for receiving tolerances for folpet insecticide on imported crops. The number and location of trials were previously approved by CBTS (G. Kramer, 7/24/95, CBTS No. 15869, DP Barcode D217392).

The qualitative nature of folpet residues in plants is adequately understood; the HED Metabolism Committee concluded that the residue of concern in plant commodities is the parent compound *per se*. The Metabolism Committee concluded that phthalic acid would not need to be regulated as it is far less toxic than parent folpet and is not a carcinogen. Additionally, phthalimide is not a residue of toxicological concern (see HED Metabolism Committee Decision memorandum from F. Fort dated 6/24/97).

Tolerances are established [40 CFR §180.191 for residues of folpet (N-(trichloromethylthiophthalimide), in or on various raw agricultural commodities. These range from 15 ppm on citrus, cucumbers, garlic, melons, onions (dry bulb), pumpkins, and summer and winter squash to 50 ppm on celery, cherries, leaks, lettuce, onions (green) and shallots. A tolerance of 25 ppm presently exists for folpet on apples, avocados, blackberries, blueberries, boysenberries, crabapples, cranberries, currants, dewberries, gooseberries, grapes, huckleberries, loganberries, raspberries, strawberries, and tomatoes.

Codex MRLs are expressed as residues of parent folpet *per se*. Issues pertaining to compatibility of U.S. tolerances with Codex MRLs will be addressed at the issuance of the RED.

CONCLUSIONS AND RECOMMENDATIONS

Storage Stability

1. The submitted data reflecting the stability of folpet in apples, cranberries, cucumbers, lettuce, onions, tomatoes, apple juice and pomace, grape juice, and tomato paste and puree during frozen storage are adequate. Although the registrant provided no storage stability data to support the storage times for strawberries, adequate data exist for cranberries and CBRS will translate cranberry storage stability data to strawberries. Since field trial storage intervals in all cases were less than those intervals over which stability has been demonstrated, CBRS concludes that there are no storage stability concerns associated with the *present* field trials for the following crops: apples, cranberries, cucumbers, lettuce, onions, strawberries, and tomatoes. CBTS has required that storage stability data be provided for melons to support the Israeli and French field trials. Storage times for apple juice and pomace, grape juice, and tomato paste and puree were not provided in this submission.

Magnitude of the Residue in Plants

- 2. Melons: The submitted data indicate that folpet residues ranged up to 2.3 ppm in/on melons harvested 7 days following the last of up to 6 applications (with a 5 to 7-day retreatment interval) of folpet at up to 1.75 kg ai/ha per application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends a tolerance level of 3 ppm provided the registrant submits 1) the storage stability data originally required by CBTS to support the 6 month storage period in the Israeli trials; 2) complete information concerning the melon field trial conducted in France; and 3) changes in the international labels such that use directions do not exceed a maximum single application rate of 1.75 kg ai/ha. and a maximum seasonal rate of 10.5 kg ai/ha; the PHI and retreatment interval must also be specified as a minimum of 7 days each. This reflects the maximum seasonal usage pattern presented in the field trial data (Mexico) and is considered to be adequate to cover uses at lower rates. We recommend that the registrant submit the required additional information and modify the current international labels in the manner indicated above.
- 3. Omions: The submitted data indicate that the folpet residues ranged up to 0.406 ppm in/on dry bulb onions harvested 7 days following the last of either 3 or 4 applications (7-day retreatment interval) of folpet at either 1.5- or 1.95 kg ai/ha per application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 2 ppm on dry bulb onions provided that international labels are changed so that use rates do not exceed a maximum single rate of 1.95 kg ai/ha and a maximum seasonal rate of 6.0 kg ai/ha. These labels should also reflect a minimum PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.
- 4. <u>Cranberries</u>: The submitted data indicate that the folpet residues ranged up to 11.2 ppm in/on cranberries harvested 30 days following the last of three broadcast applications (separated by a 12- to 14-day retreatment interval) at 5.0 kg a.i./ha/application. Although the submitted data do not reflect the maximum label use pattern of folpet on cranberries (which is limited to only two applications and not three applications as tested here), CBRS will accept the current field trials and recommend for a tolerance of 15 ppm for residues of folpet on cranberries.
- 5. Grapes: The submitted data indicate that the folpet residues ranged up to 38.3 ppm in/on grapes harvested 14 days following the last of five applications (separated by a 5-7 day retreatment interval) at 1.49 kg ai/ha/application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 50 ppm on grapes provided that the international labels are changed so that use rates do not exceed a maximum single

application rate of 1.5 kg ai/ha and a maximum seasonal rate of 8.0 kg ai/ha. These labels should also reflect a minimum PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

- 6. Lettuce: The submitted data indicate that the folpet residues ranged up to 21.9 ppm in leaf lettuce and 16.5 ppm in head lettuce harvested seven days following the last of four applications (with an ca. 7-day retreatment interval) of folpet at 1.25 kg ai/ha per application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 50 ppm on head and leaf lettuce provided that the international labels are changed so that use rates do not exceed a maximum of 4 applications per season at a rate of 1.25 kg ai/ha and a PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.
- 7. Tomatoes: The submitted data indicate that the folpet residues ranged up to 2.38 ppm in/on tomatoes harvested 7 days following the last of either 5 applications at 2.0 kg ai/ha (with a 2 day PHI) or 7 applications at 1.73 kg a.i./ha (with a 7 day PHI and approximate 5-7 day retreatment interval) of folpet. The submitted international labels, however, permit higher application rates and/or shorter PHIs that those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 5 ppm on tomatoes provided that the international labels are changed so that use directions do not exceed a maximum single application rate of 1.75 kg ai/ha, and a maximum seasonal application rate of 10 kg ai/ha. These labels should also reflect a minimum PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios. The registrant is also required to submit the additional 5 month storage stability required by CBTS in support of the Hungarian and Israeli field trials.
- 8. <u>Strawberries</u>: The submitted data indicate that the folpet residues ranged up to 2.56 ppm in/on strawberries harvested 2 days following the last of 4 applications at 1.25 kg ai/ha each. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 5 ppm on strawberries <u>provided</u> the use directions on the international labels do not exceed a maximum of 4 applications per season at up to 1.25 kg ai/application, and specify a retreatment interval of 7 days and a preharvest interval of 2 days. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.
- 9. Apples: The submitted data indicate that the folpet residues ranged up to 3.67 ppm

in/on apples harvested 7-10 days following the last of several applications (14 day retreatment interval) at 0.8 to 3.59 kg ai/ha. The submitted international labels, however, permit higher application rates and/or shorter PHIs that those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 5 ppm on apples <u>provided</u> that the international labels are changed so that use directions do not exceed a maximum single application rate of 3.6 kg ai/ha and a maximum seasonal application rate of 10.8 kg ai/ha. These labels should also reflect a minimum PHI of 10 days and a treatment interval of 14 days. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

- 10. Cucumbers: The submitted data indicate that the folpet residues ranged up to 0.699 ppm in/on cucumbers harvested 3-7 days following the last of several applications at up to 1.75 kg ai/ha. The submitted international labels, however, permit higher application rates and/or shorter PHIs that those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 2 ppm on cucumbers provided that the international labels are changed such that use directions do not exceed a maximum single application rate of 1.75 kg ai/ha/application and a maximum seasonal application rate of 8.0 kg ai/ha; these labels should also reflect a minimum PHI of 3 days and a retreatment interval of 7 days. The registrant is also required to supply the additional information required previously by CBTS (see below). We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios. The CBTS-required additional data includes:
 - 1) submission of Folpan labels for Hungary so that we can determine whether the use patterns in these trials correspond to the maximum use rate, minimum spray volume and minimum PHI.
 - 2) submission of details on the spray composition (i.e., additives) for the Gedera trial and a complete report (both field and analytical) for the Zevulun Valley trial.
 - 3) submission of storage stability data for cucumbers to support a storage period of up to 6 months.
 - 4) submission of Folpan labels for Turkey so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.
 - 5) submission of a field trial report for the Turkish trial (and not simply the field trial protocol which was submitted). This report should include all data as specified in OPPTS 860.1500 concerning crop field trials.

- 6) submission of data relating to the shipping dates from the Turkish field sites to Makhteshim-Agan, the arrival dates at Makhteshim-Agan, the shipping dates to the analytical lab and details of the storage conditions at Makhteshim-Agan
- 7) submission of a protocol of Method FP/15/91 (which appears to be identical to FP/15/93) used in the Turkish trial so that we can assess the adequacy of this method for data gathering purposes.
- 8) submission of representative chromatograms of control and treated samples from the Turkish trial for each time point.

NOTE TO CRM/PM: At the time of publication of these tolerances, there should be a footnote for all of these commodities stating that there is no U.S. registration for this chemical.

DETAILED CONSIDERATIONS

Residue Analytical Methods

The raw agricultural commodity samples from the current submissions were analyzed by EN-CAS Analytical Laboratories (Winston-Salem, NC) for residues of folpet using a GC/ECD method.

Briefly, samples were blended with sodium sulfate, o-phosphoric acid, and ethyl acetate to homogenize the matrix. The mixture was filtered and diluted to 250 mL, with a 50 mL aliquot partitioned with acidified water. The organic phase was concentrated *in vacuo*, diluted in hexane, and chromatographed on a Florisil column for clean-up. The eluate was evaporated to dryness and redissolved in hexane for analysis by GC/ECD. The limit of quantitation (LOQ) was 0.05 ppni. No information regarding the LOD was provided.

The method had been validated previously for analysis of folpet residues in a variety of fruits and vegetables to determine the adequacy of the method for residue data collection purposes. In addition, procedural recoveries were also performed to verify suitability of the method: untreated samples of RACs from each of the individual field trials were fortified with various levels of folpet. Residues of folpet were nondetectable in/on all samples of untreated RACs. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 1. These data indicate that the methods are adequate for data collection for folpet residues in/on melons, onions, cranberries, grapes, lettuce, strawberries, apples, and cucumbers.

Storage Stability Data

The RAC samples from the current field trials were promptly placed in a freezer or placed on dry ice within 6 hours of collection (except for onions which were allowed to dry in the field for one day) and shipped frozen to EN-CAS Laboratories (Winston-Salem, NC) where they were stored frozen (<-10 C) prior to analysis. Storage times from sampling to extraction for analysis were as follows:

11 to 30 days
12 to 22 days
14 to 29 days
15 to 40 days
25 to 111 days
13 to 26 days
17 to 101 days
12 to 43 days
7 to 22 days

The registrant has submitted storage stability data for various raw agricultural commodities in support of the field trial studies. The following substrates were chosen to be representative commodities for crop field trials requiring storage stability data: apples, cranberries, cucumbers, lettuce, onions, and tomatoes. Storage stability was also tested for the following processed commodities: apple juice and pomace, grape juice, and tomato paste and puree.

Samples were fortified with folpet at 1.0 ppm. The fortified and unfortified samples were stored frozen. Samples were extracted and analyzed after various time periods of frozen storage. Samples were analyzed using the methods described in "Residue Analytical Methods." The results of the storage stability study are presented in Table 2. Although only the corrected recoveries are presented in Table 2, the registrant provided both residue recoveries and fresh fortification recoveries used to calculate the corrected recovery values.

Study summary: The submitted data reflecting the stability of folpet in apples, cranberries, cucumbers, lettuce, onions, tomatoes, apple juice and pomace, grape juice, and tomato paste and puree during frozen storage are adequate. Although the registrant provided no storage stability data to support the storage times for strawberries, adequate data exist for cranberries and CBRS will translate cranberry storage stability data to strawberries. Since field trial storage intervals in all cases were less than those intervals over which stability has been demonstrated, CBRS concludes that there are no storage stability concerns associated with the present field trials for the following crops: apples, cranberries, cucumbers, lettuce, omions, strawberries, and tomatoes. CBTS has required that storage stability data be provided for melons to support the Israeli and French field trials. Storage times for apple juice and pomace, grape juice, and tomato paste and puree were not provided in this submission.

Commodity	Fortification Level (ppm)	Percent Recovery	
Melons (442352-03)	0.05 (2) 0.50 (2) 5.0 (2)	110, 111 83, 89 95, 97	
Onions (442352-02)	0.05 0.5 1.0 20	92 78 77 78	
Cranberry (442352-01)	0.05 (2) 0.50 (2) 5.0 (2)	100, 104 76, 88 79, 82	
Grapes (442352-08)	0.05 (2) 0.50 (2) 5.0 (2)	70, 92 90, 101 96, 80	
Lettuce (442352-04)	0.05 (2) 0.50 (2) 5.0 (2)	117, 110 77, 97 78, 77	
Tomatoes (442352-06)	0.05 (2) 1.0 2.0 5.0 (2)	105, 79 84 83 75, 83	
Strawberry (442352-05)	0.05 (2) 2.0 (2) 4.0 5.0	89,96 72, 72 52 53	
Apples (442352-09)	0.05 (2) 1.0 (2) 2.0 3.0 4.0 5.0	89, 105 88, 88 100 97 91 69 84	
Cucumbers (442352-07)	0.05 (2) 0.10 1.0 (2) 20	88, 123 97 100 91	

Analyte	Commodity	Fortification Level (ppm)	Storage Period (Days)	Corrected Recovery in Stored Samples (%)*
Apples	RAC	1.0	0	
			. 14	102-109 (3)
			30	94-110 (3)
•			149	102-118 (3)
	Juice -	1.0	0	
		·	7	96-112 (3)
•		1 1	14	50-99 (3)
			30	62-92 (3)
	Pomace	1.0	0	
	N. Committee		16	94-103 (3)
			30	88-93 (3)
Cranberries	RAC	1.0	0	
•			14	- 92-131 (3)
			29	· 80-103 (3)
		ľ	144	96-115 (3)
			176	100-114 (3)
Grapes	Juice	1.0	0	
			7	104-116 (3)
			36	99-104 (3)
Cucumbers	RAC	1.0	. 0	
			18	74-84 (3)
			29	96-123 (3)
Lettuce	RAC	1.0	0	
			14	90-111 (3)
			28	74-102 (3)
			90	92-116 (3)
Onions	RAC	1.0	0 .	
			14	105-112 (3)
			41	90-95 (3)
Fomatoes	RAC	1.0	· 0	
	`		13	90-94 (3)
			35	87-97 (3)
			74	74-107 (3)
			136	76-87 (3)
•	Paste	1.0	0	
			14	82-96 (3)
			30	89-106 (3)
	Puree	0.25	0	
			14	88-93 (3)
	1		32	78-90 (3)

Number of samples in parentheses. The registrant provided uncorrected storage stability and fresh fortification recoveries in its submission as well. Only corrected recoveries are presented in this table. Average fresh fortification recoveries varied between 69-108%.

Magnitude of the Residue in Plants

Melons

Established tolerance: A tolerance of 15 ppm has been established for residues of folpet in/on melons [40 CFR §180.191].

Use patterns: The registrant has earlier submitted use directions for the Folpan 48 PS(suspended powder) formulation, the Folpan 50 P.H. (wettable powder) formulation, the Folpan 80 P.H formulation, the Folpan 48 PL formulation, and the Folpan 48 SC (suspended concentrate) formulation (see Folpet import tolerance petition dated September, 1995). The labels were obtained from the locations in which the submitted field trials were performed (i.e., Mexico, Honduras, and Guatemala) and each contain 480 g ai/L or 500 g ai/kg (except for the Mexican Folpan 80 formulation which contains 800 g ai/kg). Use directions for the Mexican product specify unlimited applications at up to 1.7 kg ai/A with the final application permitted up until the day of harvest. Use directions for the Honduran and Guatemalan labels are specified in terms of volume of concentrate per 100 L of water, from which no maximum use rate can be inferred. As with the Mexican label, no PHI is specified and harvest can occur immediately following the last application.

Discussion of the data: Makheteshim has submitted data (1997; MRID 442352-03) from 6 trials conducted in Mexico (3 trials), Honduras (2 trials), and Guatemala (1 trial). These trials were designed to determine residues of folpet in/on melons following either 4 (Honduras) or 6 (Mexico and Guatemala) broadcast applications to actively-growing melon plants. These broadcast applications were made via a backpack sprayer at nominal rates of 0.48 kg ai/ha of folpet in Mexico, 0.64 kg ai/ha in Honduras, or 1.75 kg ai/ha of folpet in Guatemala (actual application rates were 91-106% of nominal). Mature melons were harvested either 3 days (Honduras and Guatemala) or 7 days (Mexico) following the last of 4 or 6 treatments, at retreatment intervals of approximately 5 days.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated melons were determined using the GC/ECD methods described above. Residues were less than the LOD <0.05 ppm) in/on all untreated melon samples. Residues in/on treated samples are presented in Table 3.

Discussion of Previously Submitted Data: According to a CBTS review (G. Kramer, 10/30/95, Barcode D219781, CBTS# 16322), the registrant has submitted a melon residue trial conducted in Israel using Folpan 80WP. The application rate was 2.0 or 4.0 kg ai/ha per application and a total of six applications were made with a retreatment interval of 7-8 days. Samples were harvested 0-, 7- and 14- days after the final application. The maximum folpet residue was 2.80 ppm (0-day PHI). Residues resulting from this treatment scenario are shown in Table 4 (reproduced from the G. Kramer memorandum).

Table 3. Residues of folpet in/on melons harvested 3-7 days following four or six applications of folpet at 0.48 to 1.75 kg ai/ha per application (seasonal total of 2.9 to 10.5 kg ai/ha).							
Trial Location	Application Rate (No. x kg a.i./ha)	Trial No.	РНІ	Residues (ppm)			
		01	7	2.23			
Mexico				0.944			
	6 x 1.75	02	7	0.886			
		. 02		0.724			
		03	7	0.301			
			,	0.404			
		04	3	0.322			
Honduras	4 x 0.64	04	3	0.174			
Holidulas	4 x 0.04	05	3	0.202			
		03	3	0.410			
Guatemala	6 x 0.48	06	3	0.225			
Guatemaia	0 % 0.46	VU	3	0.207			

Table 4. Folpet Residue Data for Melon Trials Conducted in Israel (from G. Kramer memo dated 10/30/95)							
Crop (Location)	Application Rate (kg ai/ha)	No. Applications	Between Application Interval (weeks)	PHI (days)	Maximum Residue (ppm)		
Melons	2.0	6	1	. 0	1.77		
(Israel)		•		7	0.66		
				14	0.72		
	4.0	6	1	0	2.80		
				7	1.84		
				14	0.60		

CBTS required that certain additional information be submitted before the acceptability of this melon residue trial could be assessed. This information was submitted by the registrant and CBTS concluded (see G. Kramer, CBTS No. 17092, DP Barcode D224782) that the cited deficiencies were resolved provided that adequate storage stability data is submitted (i.e., storage stability data adequate to support the 6 month storage period of melons prior to analysis).

Per CBTS (G. Kramer, 10/30/95, CBTS No. 16322, DP Barcode D219781), the registrant has also submitted an analytical report on the analysis of 12 melon samples from France. There is no information on the origin of these samples. The registrant was required by CBTS to submit a complete field trial report prior to our review of these data. CBTS noted that this report includes data which indicate that folpet is rapidly degraded during frozen storage in homogenized RACs and that the required sample storage information for all folpet residue studies must thus include the state of the RACs (whole or homogenized) during frozen storage.

Study summary (1997; MRID 44235203): The submitted data indicate that folpet residues ranged up to 2.3 ppm in/on melons harvested 7 days following the last of up to 6 applications (with a 5 to 7-day retreatment interval) of folpet at up to 1.75 kg ai/ha per application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends a tolerance level of 3 ppm provided the registrant submits 1) the storage stability data originally required by CBTS to support the 6 month storage period in the Israeli trials; 2) complete information concerning the melon field trial conducted in France; and 3) changes in the international labels such that use directions do not exceed a maximum single application rate of 1.75 kg ai/ha, and a maximum seasonal rate of 10.5 kg ai/ha; the PHI and retreatment interval must also be specified as a minimum of 7 days each. This reflects the maximum seasonal usage pattern presented in the field trial data (Mexico) and is considered to be adequate to cover uses at lower rates. We recommend that the registrant submit the required additional information and modify the current international labels in the manner indicated above.

Onions

Established tolerances: A tolerance of 15 ppm has been established for residues of folpet in/on dry bulb onions [40 CFR §180.191].

Use patterns: The registrant has previously submitted use directions for the Folpan 50 P.H. (wettable powder) and Folpan 500 WP formulation. The latter is registered for use in Chile, while the former is registered for use in Mexico. Each formulation contains 500 g ai/kg product. The Mexican Folpan 50 P.H. product specifies unlimited applications at up to 1.5 kg ai/ha with a retreatment interval of 5-7 days. Harvest is permitted immediately following the last application. The Chilean Folpan 500 WP use directions permit unlimited applications (at retreatment intervals of 7 days) of up to 2 kg ai/ha each. As with the Mexican product,

no PHI is specified and harvest can occur immediately following the last applications.

Discussion of the data: Makheteshim has submitted data (1997; MRID 442352-02) from 3 trials conducted in Mexico (2 trials), and Chile. These studies were conducted to determine residues of folpet in/on onions following either 4 (Mexico) or 6 (Chile) broadcast applications to actively-growing onions. Re-treatment intervals were approximately 7 days. These broadcast applications were made via a backpack sprayer at nominal rates of 1.5 kg ai/ha of Folpan 50 WP in Mexico or 1.95 kg ai/ha of Folpan in Chile (actual application rates were 99-102% of nominal). Mature onions were harvested 7 days following the last of the treatments, dried for one day on the ground (as per standard agricultural practice), and subsequently frozen for shipment to EN-CAS for analysis.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated onions were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppin) in/on all untreated onion samples. Residues in/on treated samples are presented in Table 5.

Table 5. Residues of Folpet in/on Dry Bulb Onions Harvested 7 Days Following Three or Four Applications of Folpet at 1.5 to 1.95 kg/ha application (6.0 kg ai/ha total).							
Trial Application Rate Location (No. x kg ai/ha) Trial No. PHI Residues (ppm)							
	4 x 1.5	0.1	01 7 7 7 7 7	0.406			
		10		0.307			
Mexico		02		0.410			
,				0.321			
Chile	3 x 1.95	03		0.362			
			7	0.270			

Discussion of Previously Submitted Data: The registrant has not previously submitted any foreign data to support import tolerances on dry bulb onions.

Study summary (1994; MRID 43842801): The submitted data indicate that the folpet residues ranged up to 0.406 ppm in/on dry bulb onions harvested 7 days following the last of either 3 or 4 applications (7-day retreatment interval) of folpet at either 1.5- or 1.95 kg ai/ha per application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends for a tolerance of 2 ppm on dry bulb onions provided that international labels are changed so that use rates do not exceed a maximum single rate of 1.95 kg ai/ha and a maximum seasonal rate of 6.0 kg ai/ha. These labels shouldalso reflect a minimum PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the

tested scenarios.

Cranberries

Established tolerances: A tolerance of 25 ppm has been established for residues of folpet in/on cranberries [40 CFR §180.191].

Use patterns: The registrant has submitted use directions for the Folpan 50 WP formulation which is registered for use on cranberries in Canada. This formulation contains 500 g ai/kg product and the label directions specify an application rate of 5 kg ai/ha (when 5% of the blossoms are open), repeated 10-14 days later (when 50-75% of blossoms are open). A PHI of 30 days is indicated.

Discussion of the data: Makheteshim has submitted data (1997; MRID 44235201) from 3 trials conducted near Vancouver, B.C., Canada, a region which produces 99% of the cranberries going to the U.S. for export. These studies were performed to determine residues of folpet in/on cranberries following three broadcast applications to actively-growing cranberries (CBRS notes that current label directions indicate that only two applications are permitted). These broadcast applications were made via a backpack sprayer at nominal rates of 5.0 kg ai/ha (actual application rates ranged from 95 to 112% of nominal). Mature cranberries were harvested 29-30 days following the second of two treatments and divided into two 0.5 kg samples. One sample (the "wet-sampled" group) was placed into open mesh nylon bags and suspended for 24 hours in reservoirs of water used for cranberry bog flooding designed to simulate commercial wet harvest. The second sample (the "dry-sampled" group) was not soaked and was instead analyzed directly. Samples were shipped frozen to EN-CAS Laboratories for analysis. The registrant indicated that residues in wet-sampled cranberries were significantly lower than those resulting from dry sampling and since more than 95% of the Canadian and U.S. crops are harvested by wet-sampling, actual residues are likely to be much lower than the dry-sample based tolerance.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated cranberries were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated cranberry samples. Residues in/on treated samples are presented in Table 6.

Table 6. Residues of Folpet in/on Wet- and Dry-sampled Cranberries Harvested 30 Days Following Three Applications of Folpet at 5.0 kg a.i./ha per application (15.0 kg a.i./ha total).							
Trial	Application Rate	Trial No.	PHI	Residues (ppm)			
Location	(No. x kg ai/ha)	illiai (NO,	marko, rm		Wet- sampled		
		01	30	3.85	0.83		
		0,	. 30	7.21	1.20		
Canada	3 x 5.0	5.0	30	3.40	1.35		
Canada	Canada 3 x 5.0 02 03	02	. 30	3.80	1.34		
		02	30	11.0	1.85		
			11.2	1.81			

Discussion of Previously Submitted Data The registrant has not previously submitted any foreign data to support import tolerances on cranberries.

Study summary (1997; MRID 44235201): The submitted data indicate that the folpet residues ranged up to 11.2 ppm in/on cranberries harvested 30 days following the last of three broadcast applications (separated by a 12- to 14-day retreatment interval) at 5.0 kg a.i./ha/application. Although the submitted data do not reflect the maximum label use pattern of folpet on cranberries (which is limited to only two applications and not three applications as tested here), CBRS will accept the current field trials and recommend for a tolerance of 15 ppm for residues of folpet on cranberries.

Grapes

Established tolerances: A tolerance of 25 ppm has been established for residues of folpet in/on grapes [40 CFR §180.191].

Use patterns: The registrant has previously submitted use directions for several of the folpet products registered for use on grapes. No maximum use rate (on a kg/ha basis) is specified on the Argentine label (Super Folpan). The Mexican labels specify unlimited applications at up to 1.2 kg/ha at intervals of 7-10 days; no PHI is indicated. The Chilean label specifies a maximum treatment rate of 2 kg ai/ha per application with a 7 day retreatment interval and an unlimited number of applications. No English translations were provided for the Italian labels.

Discussion of the data: Makheteshim has submitted data (1997; MRID 44235208) from 6 field trials conducted in Italy (2), Mexico, Chile (2), and Argentina. One trial of table grapes and one trial of wine grapes were conducted each in Italy and Chile. The Argentine trial was conducted with table grapes, and the Mexican trial with grapes normally grown for raisins (we note that CBTS reached an agreement with the registrant to conduct 2 field trials in France, but no data concerning residues in grapes from field trials conducted in France were submitted

-- the registrant's submission simply states that these field trials were deleted at the sponsor's request). The submitted studies were performed to determine residues of folpet in/on grapes following 3-, 4-, 5-, or 7- broadcast applications to actively-growing grapes. These foliar applications were made via a backpack sprayer at nominal rates of 1.0-1.95 kg ai/ha (actual application rates ranged from 98 to 108% of nominal). Retreatments occurred at approximately weekly intervals. Mature grapes were harvested 7- (Argentina), 10- (Italian table grapes and Mexico), 14- (Chile), or 40- (Italian wine grapes) days following the last of multiple treatments. Samples were shipped frozen to EN-CAS Laboratories for analysis.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated grapes were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated samples. Residues in/on treated samples are presented in Table 7.

	f folpet in/on grapes harvested 7 1.0-1.95 kg a.i./ha application (ple application
Trial Location	Application Rate (No. x kg a.i./ha)	PHI	Trial No.	Residues (ppm)
		10	02	3.28
	5 x 1.6	10	03	2.88
Italy	5 X 1.6	40	04	1.73
		40		1.68
5.4	7	10	05	< 0.05
Mexico	7 x 1.0			< 0.05
		:	0.0	1.82
Chile	2 105		06	2.62
Chile	3 x 1.95	14	20	1.53
			08	2.97
	4 - 100	. 7		1.64
Argentina	4 x 1.02	7	07	1.45

Discussion of Previously Submitted Data: A single field residue trial was conducted in 1991 in Spain using Folpan 50WP (MRID# 437745-07) and was reviewed previously (and deemed supplementary) by CBTS (G. Kramer, 10/25/95, CBTS No. 16207 and 16256, DP Barcodes D219204 and D219367). The application rate was 0.4 kg ai/ha and a total of three applications were performed with a between application interval of 12 days. Four replicate samples were harvested from each treated plot 0- 10- and 20- days after the final application. CBTS concluded that the following information must be submitted before the acceptability of this grape residue trial can be assessed:

¹⁾ The Folpan label for Spain was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the

maximum use rate, minimum spray volume, and minimum PHI.

- 2) The registrant must provide an analytical report for the trial which includes the protocol, validation data and representative chromatograms of treated and control samples for each time point.
- 3) The registrant should provide the arrival dates at the analytical lab, details of the storage conditions, and the dates of analysis. If the samples were stored for longer than one month prior to analysis, then evidence of storage stability must be provided.

CBTS also reviewed a single field residue trial conducted in 1992 in Chile using Folpan 80 WP (MRID# 437870-01). This was reviewed by CBTS (G. Kramer, CBTS No. 10/25/95. CBTS Nos. 16207 and 16256, DP Barcodes D219204 and D219367) and also subsequently deemed supplementary. The application rate was 2.88-3.6 kg ai/ha per application and a total of three applications were performed with a re-treatment interval of 3 weeks. Samples were harvested 15 days after the final application. The samples were stored as homogenates for 4 months prior to analysis. Analysis of the treated samples (Table 8) showed that the maximum folpet residue was 25.2 ppm. CBTS concluded that the following information must be submitted before the acceptability of this grape residue trial can be assessed:

- 1) The Folpan label for Chile was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.
- 2) The registrant must provide a further details of the field portion of the study, including the spray volume and the identity of any adjuvants employed for each application, weather data, and the conditions of sample storage between harvest (3/24) and the arrival at the analytical lab (4/8).
- 3) As the samples were stored for longer than one month prior to analysis, evidence of storage stability must be provided.
- 4) The registrant should provide a protocol and validation data for Method CAC/PR-7-1984 so that we can assess the adequacy of this procedure for data gathering purposes.
- 5) Chromatograms (with English labels) of each treated and control sample should be submitted.

Two field residue trials were conducted in 1991/92 in Argentina using Super Folpan WP (MRID # 437755-01), were reviewed by CBTS (G. Kramer, 10/25/95, CBTS Nos. 16207 and 16256, DP Barcodes D219204 and D219367), and were determined by CBTS to be supplementary. In the first trial (wine grapes), three applications at 1.28 kg ai/ha were made with a re-treatment interval of 4-5 weeks. Samples were harvested 20 days after the final application. In the second trial (table grapes), five applications at 1.66 kg ai/ha were made with a between application interval of 3-4 weeks. Samples were harvested 7 days after the final application. The samples were analyzed within one month of harvest. Analysis of the treated samples (Table 8) showed that the maximum folpet residue was 0.06 ppm in wine grapes and 0.57 ppm in table grapes. CBTS concluded that the following information must be submitted before the acceptability of the grape residue trial could be assessed:

1) The Folpan label for Argentina was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in these trials correspond

to the maximum use rate, minimum spray volume and minimum PHI.

2) The registrant should provide further details of the analytical method validation; i.e. were fortified controls employed and what were the values in ppm.

Four field residue trials were conducted in 1991 in CA (2), NY, and Canada (Ontario) using Folpan 50WP. This study was also reviewed by CBTS (MRID # 43614701, G. Kramer, 8/15/95, CBTS No. 15719, DP Barcode D216442). The application rate was 1.33 lbs ai/A or 2.00 lbs. ai/A in NY (corresponding to 1.49 and 2.25 kg ai/ha, respectively) and a total of five applications were performed with a between application interval of 3-7 days. Three treated plots were established at each site with replicate samples harvested from each treated plot 14 days after the final application. Analysis of the treated samples (Table 8) showed that the maximum folpet residue was 38.3 ppm (Canada).

Table 8. Folpet Residue Date (from G. Kramer, memoranda dated 10/25/96 and 8/15/95)						
Crop (Location)	Application Rate (kg. ai/ha)	# Applications	Between Application Interval	PHI (Days)	Maximum Residue (ppm)	
Grapes (Chile)	2.88-3.6	3	3 weeks	15	25.23	
Wine Grapes (Argentina)	1.28	3	4-5 weeks	20	0.063	
Table Grapes (Argentina)	1.66	5	3-4 weeks	7	0.566	
Grapes (CA)	1.49	5	3-4 days	14	5.40	
Grapes (CA)	1.49	5	5-7 days	14	3.44	
Grapes (NY)	2.25	5	5-7 days	14	9.62	
Grapes (Canada)	1.49	5	5-7 days	14	38.3	

N.D. = Not Detected

Study summary (1994; MRID 43842801): The submitted data indicate that the folpet residues ranged up to 38.3 ppm in/on grapes harvested 14 days following the last of five applications (separated by a 5-7 day retreatment interval) at 1.49 kg ai/ha/application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the tested aplication scenarios, CBRS recommends for a tolerance of 50 ppm on grapes provided that the international labels are changed so that use rates do not exceed a maximum single application rate of 1.5 kg ai/ha and a maximum seasonal rate of 8.0 kg ai/ha. These labels should also reflect a minimum PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

Lettuce

Established tolerances: A tolerance of 50 ppm has been established for residues of folpet in/on lettuce [40 CFR §180.191].

Use patterns: The registrant has submitted use directions for the Folpan 48 P.S. (suspended powder), Folpan 50 P.H. (wettable powder), and Folpan 80 P.H. formulations which are registered for use in Mexico. These three formulations contain 480 g a.i./L, 500 g a.i./kg, and 800 g a.i./kg, respectively, and application rates of up to 1.6 kg a.i./ha (corresponding to the Folpan 80 P.H. product) are permitted. No PHI is specified (and harvest can therefore occur immediately following the last application) and an unlimited number of applications at 7 day retreatment intervals is permitted.

Discussion of the data: Makheteshim has submitted data (1997; MRID 442352-04) from 4 trials conducted in Mexico. These studies were conducted to determine residues of folpet in/on lettuce following 4 broadcast foliar applications to actively-growing lettuce plants: one trial was performed with leaf lettuce and 3 trials were conducted with head lettuce. These broadcast applications were made via a backpack sprayer at nominal rates of 1.25 kg ai/ha of Folpan 50 WP normally sold in Mexico. Actual application rates were 98-103% of nominal. Lettuce was harvested 7 days following the last of the treatments (with a 7 day retreatment interval), and subsequently frozen for shipment to EN-CAS for analysis. Of the three trials conducted with head lettuce, wrapper leaves were removed from samples from two of the trials; since tolerances are generally established with wrapper leaved intact (unless obviously damaged), results from only one sample of head lettuce are available.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated lettuce were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated onion samples. Residues in/on treated samples are presented in Table 9.

Table 9. Residues of folpet in/on head and leaf lettuce harvested 7 days following four applications of folpet at 1.25 kg a,i./ha per application (10 kg a.i./ha total).							
Trial Location	Commodity	Application Rate No. x kg ai/ha	Trial No.	РНІ	Residues (ppm)		
	Leaf Lettuce	ettuce 4 x 1.25 01		7	19.4		
	Lear Lenuce	4 X 1.23	VI		21.9		
	Head Lettuce ^b	4 x 1.25	02	7	3.22		
,					9.82		
Mexico			03	7	1.58		
Mexico					4.52		
				7	16.5ª		
	Head Lettuce	4 x 1.25	04		15.1a		
		4 A 1.23			0.216 ^b		
		,	,	•	0.260b		

Sample taken with wrapper leaves

Study summary (1994; MRID 43842801): The submitted data indicate that the folpet residues ranged up to 21.9 ppm in leaf lettuce and 16.5 ppm in head lettuce harvested seven days following the last of four applications (with an ca. 7-day retreatment interval) of folpet at 1.25 kg ai/ha per application. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends for a tolerance of 50 ppm on head and leaf lettuce provided that the international labels are changed so that use rates do not exceed a maximum of 4 applications per season at a rate of 1.25 kg ai/ha and a PHI and retreatment interval of 7 days. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

Tomatoes

Established tolerances: A tolerance of 25 ppm has been established for residues of folpet in/on tomatoes [40 CFR §180.191].

Use patterns: The registrant has previously submitted use directions for the Folpan 500 WP registered for use in Chile and the Folpan 48 P.S., 50 P.H., and 80 P.H. formulations registered for use in Mexico. The formulations contain, respectively, 500 g/kg, 480 g ai/L, 500 g ai/kg, and 800 g ai/kg product. The Chilean formulation specifies unlimited applications at up to 1.75 kg ai/ha with a retreatment interval of 7 days. Harvest is permitted immediately following the last application. The Mexican use directions permit unlimited applications (at retreatment intervals of 5-7 days) of up to 2.4 kg ai/ha per application. As with the Chilean product, no PHI is specified and harvest can occur

^b Sample taken without wrapper leaves

immediately following the last application.

Discussion of the data: Makheteshim has submitted data (1997; MRID 442352-06) from a total of 6 trials conducted in Mexico (5 trials), and Chile. (NOTE: CBTS had indicated to the registrant (see G. Kramer memo dated 6/13/95) that 6 additional field trials would be required, but these were required to be conducted in Mexico (5 trials) and Italy (1 trial)—not Chile. The registrant has given no indication as to why it substituted a Chilean field trial in place of an Italian one. These studies were performed to determine residues of folpet in/on tomatoes following either 5 (Mexico) or 7 (Chile) broadcast applications to actively-growing tomato plants. The broadcast applications were made via a backpack sprayer at nominal rates of 2.0 kg ai/ha of Folpan 50 WP in Mexico or 1.73 kg ai/ha of in Chile (actual application rates ranged from 98-102% of nominal). Tomatoes were harvested either 2 (Mexico) or 7 (Chile) days following the last of the treatments, and subsequently frozen for shipment to EN-CAS for analysis.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated tomatoes were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated tomato samples. Residues in/on treated samples are presented in Table 10.

Table 10. Residues of folpet in/on tomatoes harvested 2 or 7 days following five or seven applications of folpet at 1.75- or 2.0- kg ai/ha application (10-12.1 kg ai/ha total).							
Trial Location	Application Rate No. x kg a.i./ha	Trial No.	PHI	Residues (ppm)			
				0.860			
		01	2	1.01			
				0.445			
-		02	2	0.328			
				0.644			
Mexico	5 x 2.0	03	2	1.27			
				0.814			
ļ		04	2	1.58			
		0.5	2	1.08			
		05	2	1.83			
		1		1.43			
Chile	7 x 1.73	06	'	2.38			

Discussion of Previously Submitted Data CBTS has previously agreed to consider residue trials conducted in Israel and Hungary in regards to establishing a tolerance on imported tomatoes (Memo, G. Kramer 6/13/95), and has previously reviewed this data (G. Kramer, 10/30/95, CBTS No. 16322, DP Barcode D219781).

A single field residue trial was conducted in 1991 in Israel using Folpan 80WP. The application rate was 2.0 or 4.0 kg ai/ha and a total of three applications were performed with a between application interval of 7 days. Four replicate plots were established and samples were harvested from each treated plot 0-, 4- and 11- days after the final application. The samples were analyzed within five months of harvest. Analysis of the treated samples (Table 11) showed that the maximum folpet residue was 1.30 ppm (0-day PHI) or 0.84 ppm (4-day PHI). CBTS concluded that the following information must be submitted before the acceptability of this tomato residue trial can be assessed (see G Kramer, 5/13/96, CBTS No. 17092, DP Barcode D224782):

• The samples were stored for 5 months prior to homogenization with the resulting extracts subsequently stored for an additional 6 days prior to analysis. Adequate storage stability data for this time period must be demonstrated.

An additional single field residue trial was conducted in 1991 in Hungary using Folpan 50WP. This study, too, was reviewed by CBTS (G. Kramer, memo dated 10/30/95). The application rate was 0.625 kg ai/ha and a total of five applications were performed with a between application interval of 10 days. Four replicate plots were established and samples were harvested from each treated plot 0-, 7- and 14- days after the final application. The samples were analyzed within four months of harvest. Analysis of the treated samples (Table 10) showed that the maximum folpet residue was 0.08 ppm (0-day PHI). CBTS concluded that the following information must be submitted before the acceptability of this tomato residue trial can be assessed (see G. Kramer, 5/13/96, CBTS No. 17092, DP Barcode D224782):

• The samples were stored for 4 months prior to homogenization and the resulting extracts stored for 2 days prior to analysis. The registrant is required to demonstrate storage stability over this time period.

Study summary (1994; MRID 43842806): The submitted data indicate that the folpet residues ranged up to 2.38 ppm in/on tomatoes harvested 7 days following the last of either 5 applications at 2.0 kg ai/ha (with a 2 day PHI) or 7 applications at 1.73 kg a.i./ha (with a 7 day PHI and approximate 5-7 day retreatment interval) of folpet. The submitted international labels, however, permit higher application rates and/or shorter PHIs that those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends for a tolerance of 5 ppm on tomatoes provided that the international labels are changed so that use directions do not exceed a maximum single application rate of 1.75 kg ai/ha, and a maximum seasonal application rate of 10 kg ai/ha. These labels should also reflect a minimum PHI and retreatment interval of 7 days each. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios. The registrant is also required to submit the additional 5 month storage stability required by CBTS in support of the Hungarian and Israeli field trials.

Table 10. Fo	Table 10. Folpet Residues in Tomatoes (from G. Kramer memo dated 10/30/95)						
Crop (Location)	Application Rate (kg ai/ha)	# Applications	Between Application Interval (Weeks)	PHI (Days)	Maximum Residue (ppm)		
Tomatoes	2.0	3	1	0	0.71		
(Israel)				4	0.29		
			<u> </u>	11	0.21		
	4.0	3	1	0	1.30		
			,	4	0.84		
				11	0.30		
Tomatoes	0.625	5	1	0	0.08		
(Hungary)				7	< 0.02		
				14	< 0.02		

Strawberries

Established tolerances: A tolerance of 25 ppm has been established for residues of folpet in/on strawberries [40 CFR §180.191].

Use patterns: The registrant has submitted use directions for the Folpan 48 P.S (suspended powder), Folpan 50 P.H. (wettable powder), and Folpan 80 P.H. formulations. These products contain, respectively, 480 g ai/L, 500 g a.i./kg, and 800 g ai/kg product, respectively. The formulations specify unlimited applications at up to 1.6 kg a.i./ha with no specified retreatment intervals. Harvest is permitted immediately following the last application.

Discussion of the data: Makhteshim has submitted data (1997; MRID 442352-05) from a total of 3 trials conducted in Mexico. These studies were performed to determine residues of folpet in/on strawberries following four broadcast applications to actively-growing strawberries. These broadcast applications were made via a backpack sprayer at nominal rates of 1.2-1.7 kg ai/ha of Folpan 50 WP in Mexico (actual application rates ranged from

97-102% of nominal). Retreatment intervals were approximately 7 days, strawberries were harvested 2 days following the last of the treatments, and subsequently frozen for shipment to EN-CAS for analysis.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated strawberries were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated strawberry samples. Residues in/on treated samples are presented in Table 11.

Table 11. Residues			vested 2 days following t tion (5 kg ai/ha total)	four applications of folpet at	
Trial Location	Application Rate No. x kg a.i./ha	Trial No.	PHI	Residues (ppm)	
Mexico		01	2	0.763	
	·			1.13	
		01 (repeat)	2	2.56	
	4 x 1.25			2.54	
		02	2	0.917	
				1.56	
		03	2	2.00	
				2.18	

Study summary (1997; MRID 442352-05): The submitted data indicate that the folpet residues ranged up to 2.56 ppm in/on strawberries harvested 2 days following the last of 4 applications at 1.25 kg ai/ha each. The submitted international labels, however, permit higher application rates and/or shorter PHIs than those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends for a tolerance of 5 ppm on strawberries provided the use directions on the international labels do not exceed a maximum of 4 applications per season at up to 1.25 kg ai/application, and specify a retreatment interval of 7 days and a preharvest interval of 2 days. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

<u>Apples</u>

Established tolerances: A tolerance of 25 ppm has been established for residues of folpet in/on apples [40 CFR §180.191].

Use patterns: The registrant has submitted use directions for the Super Folpan, Folpan 48 SC (suspended concentrate), Folpan 500 W.P., and Folpan 50 WP formulations. These products

are registered for use in the countries in which field trials were conducted and contain, respectively, 800 g ai/kg, 480 g ai/L, 500 g a.i./kg, and 500 g ai/kg. The formulations with the highest application (i.e., the Folpan SC or Folpan 500 W.P.) specify rates of up to 2.0 kg ai/ha with no limits on the number of applications or the time of harvest. A retreatment interval of 3 days is indicated.

Discussion of the data: Makheteshim has submitted data (1997; MRID 442352-09) from a total of 8 trials conducted in Canada, Chile, and Argentina as required by CBTS. These studies were performed to determine residues of folpet in/on apples following either 3 or 8 applications at nominal rates of 0.8-, 1.98-, or 3.59 kg ai/ha to actively-growing apple trees. These applications were made via airblast or backpack sprayer. Apples were harvested 7 or 10 days following the last of the treatments (with a retreatment interval of 14 days), and subsequently frozen for shipment to EN-CAS for analysis.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated apples were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated apples samples. Residues in/on treated samples are presented in Table 12.

Table 12. Residues of folpet in/on apples harvested 7 or 10 days following three or four applications of folpet at nominal application rates of 0.8-, 1.98, or 3.59 kg/ha (6.0 to 10.8 kg ai/ha total).					
Trial Location	Application Rate No. x kg a.i./ha	Trial No.	PHI	Residues (ppm)	
		01	7	1.43	
				1.31	
		02		0.359	
			. 7 .	0.431	
Canada	8 x 0.8	03	-	1.10	
			7	0.611	
			7	0.645	
		04	.7	0.451	
		05	7	1.58	
				1.98	
Chile	3 x 1.98	06	7	3.19	
				3.67	
Argentina		07	10	1.10	
	. •			1.44	
	3 x 3.59	08	10	NA ^a	
				2.61	

Not Analyzed. Samples arrived at the laboratory thawed and were therefore not analyzed.

Study summary (1997; MRID 442352-09): The submitted data indicate that the folpet residues ranged up to 3.67 ppm in/on apples harvested 7-10 days following the last of several

applications (14 day retreatment interval) at 0.8 to 3.59 kg ai/ha. The submitted international labels, however, permit higher application rates and/or shorter PHIs that those represented by the data reviewed here. Based on the *tested application scenarios*, CBRS recommends for a tolerance of 5 ppm on apples provided that the international labels are changed tso that use directions do not exceed a maximum single application rate of 3.6 kg ai/ha and a maximum seasonal application rate of 10.8 kg ai/ha. These labels should also reflect a minimum PHI of 10 days and a treatment interval of 14 days. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

Cucumbers

Established tolerances: A tolerance of 15 ppm has been established for residues of folpet in/on cucumbers [40 CFR §180.191].

Use patterns: The registrant has submitted use directions for the Folpan 48 P.S. (suspended powder), Folpan 50 P.H., Folpan 80 P.H., and Folpan 50 WP formulations. These products contain, respectively, 480 g ai/L, 500 g a.i./kg, 800 g a.i./kg, and 500 g ai/kg, respectively and are registered for use in Mexico and Canada. The Mexican formulations (i.e., the Folpan 48, Folpan 50, or Folpan 80) specify rates of up to 2.2 kg ai/ha with no limits on the number of applications or the time of harvest. A retreatment interval of 5-7 days is indicated.

Discussion of the data: Makhteshim has submitted data (1997; MRID 442352-07) from a total of 5 trials conducted in Mexico (4) and Canada. These studies were performed to determine residues of folpet in/on cucumbers following either 4 or 8 applications (ca. 5-7 day retreatment intervals) at nominal rates of 1.75- or 1.0- kg ai/ha, respectively, to actively-growing cucumbers. These applications were made via backpack sprayer, and cucumbers were harvested 3- (Mexico) or 7- (Canada) days following the last of the treatments. The collected samples were subsequently frozen for shipment to EN-CAS for laboratory analysis.

Both control (from untreated plots) and duplicate treated samples (from treated plots) were collected from each test site. Residues of folpet in/on treated and untreated cucumbers were determined using the GC/ECD methods described above. Residues were less than the LOD (<0.05 ppm) in/on all untreated cucumber samples. Residues in/on treated samples are presented in Table 13.

Table 13. Residues of folpet in/on cucumbers harvested 3 or 7 days following multiple applications of folpet at 1.0- or 1.75 kg/ha application (7.0-8.0 kg ai/ha total).				
Trial Location	Application Rate No. x kg a.i./ha	Trial No.	PHI Residues (ppm)	
Mexico	4 x 1.75	01	3	0.699
				0.409
		02	3	0.545
				0.556
		03	3	0.183
			J	0.362
		04	3	0.112
			3	0.075
Canada	8 x 1.0	05	7	, <0.05
			, ,	0.073

Discussion of Previously Submitted Data CBTS agreed to consider residue trials conducted in Turkey, Hungary, Cyprus, and Israel in regards to establishing a tolerance on imported cucumbers (see G. Kramer 6/13/95).

The single field residue trial in Turkey was conducted in 1993 using Folpan 50WP. The application rate was 2.5 kg ai/ha and a total of five applications were performed with a between application interval of 7 days. Four replicate samples were harvested from each treated plot 0-, 3-, and 7- days after the final application. This information was included in a field trial protocol and an actual field trial report was not included. The samples were analyzed within one month of harvest. Analysis of the treated samples showed that the maximum folpet residue was 0.28 ppm (0-day PHI) or 0.22 ppm (3-5 day PHI) as shown in Table 14.

A single field residue trial was conducted in 1993 using Folpan 50WP. The application rate was 1.25 kg ai/ha and a total of four applications were performed with a between application interval of 5 days. Four replicate samples were harvested from each treated plot 2-, 5-, 10- and 14- days after the final application. This information was included in a field trial protocol and we note that an actual field trial report was not included. The samples were analyzed within 6 months of harvest. Analysis of the treated samples (Table 14) showed that the maximum folpet residue was 0.74 ppm (2-day PHI).

A single field residue trial was conducted in 1993 in Israel (Gedera) using Folpan 50WP. The application rate was 1.25 kg ai/ha and a total of four applications were performed with a between application interval of 7 days. Four replicate samples were harvested from each treated plot 0-, 3-, 7-, and 10- days after the final application. The samples were analyzed within 2 months of harvest. Analysis of the treated samples (Table 14) showed that the

maximum folpet residue was 0.06 ppm (0-day PHI). However, CBTS noted that a table (on page 15) in the report contained data for folpet residues in cucumbers from Zevulun Valley. The maximum residue of folpet was 0.12 ppm (7 day PHI). Details of this trial were not provided.

A single field residue trial was conducted in 1993 in Cyprus using Folpan 50WP. The application rate was 1.00 kg ai/ha and a total of 6-7 applications were performed with a between application interval of 7 days. Four replicate samples were harvested from each treated plot 0-, 3-, 7-, and 10- days after the final application. The samples were analyzed within 3 months of harvest. Analysis of the treated samples (Table 14) showed that the maximum folpet residue was 0.36 ppm (0-day PHI) or 0.11 ppm (3 day PHI).

CBTS concluded that the following information must be submitted before the acceptability of the cucumber residue trials can be assessed:

- 1) Folpan labels for Hungary were not provided. The registrant must submit copies of these labels (and English translations) so that we can determine whether the use patterns in these trials correspond to the maximum use rate, minimum spray volume and minimum PHI.
- 2) For the Israel trials, details on the spray composition (i.e., additives) are required for the Gedera trial and a complete report (both field and analytical) is required for the Zevulun Valley trial.
- 3) The cucumber samples were stored for up to 6 months. Folpet residues appear to decline significantly in avocados over periods of 58 days (Memo, F. Fort 9/21/94) and 195 days (Memo, R. Perfetti 7/27/92). The registrant must provide storage stability data for cucumbers.
- 4) The Folpan label for Turkey was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.
- 5) The registrant must provide a field trial report for the Turkish trial (and not simply the field trial protocol which was submitted). This report should include all data as specified in OPPTS 860.1500 concerning crop field trials.
- 6) The registrant should provide the shipping dates from the field sites to Makhteshim-Agan, the arrival dates at Makhteshim-Agan, the shipping dates to the analytical lab and details of the storage conditions at Makhteshim-Agan to support the Turkish trial.
- 7) The registrant should provide a protocol of Method FP/15/91 (which appears to be identical to FP/15/93) used in the Turkish trial so that we can assess the adequacy of this method for data gathering purposes.
- 8) Representative chromatograms of control and treated samples from the Turkish trial should be submitted for each time point.

Study summary (1997; MRID 442352-07): The submitted data indicate that the folpet residues ranged up to 0.699 ppm in/on cucumbers harvested 3-7 days following the last of several applications at up to 1.75 kg ai/ha. The submitted international labels, however, permit higher application rates and/or shorter PHIs that those represented by the data reviewed here. Based on the tested application scenarios, CBRS recommends for a tolerance of 2 ppm on

cucumbers <u>provided</u> that the international labels are changed such that use directions do not exceed a maximum single application rate of 1.75 kg ai/ha/application and a maximum seasonal application rate of 8.0 kg ai/ha; these labels should also reflect a minimum PHI of 3 days and a retreatment interval of 7 days. The registrant is also required to <u>supply the additional information required previously by CBTS</u>. We recommend that the registrant modify the current international labels in the manner indicated to reflect the tested scenarios.

Table 14. Folpet Residue Data for Cucumbers (from G. Kramer memorandum)					
Location	Application Rate (kg. ai/ha)	# Applications	Between Application Interval (days)	PHI (Days)	Maximum Residue (ppm)
Turkey	2.5	5?	1?	0	0.28
				3	0.19
		·		7	0.14
Hungary	1.25	4	5	2	0.74
	·		į	. 5	0.22
				10	0.13
				14	< 0.05
Israel	1.25	. 4	7	0	0.06
,		·		3	< 0.05
				7	< 0.05
		<u> </u>		10	0.05
Cyprus	1.00	6-7	- 7	0	0.36
· 				3	0.11
				7	< 0.05
				10	< 0.05

cc: RF, SF, List A Rereg. File, Circ., V. Eagle (SRRD), DJM. RDI: Pilot Team: 4/21/97,RPerfetti:4/23/97.



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